K060071

510 (k) SUMMARY JAN 26 2006

The following information summarizes the safety and effectiveness information upon which the substantial equivalence determination for the Nexa Compression Screw is based.

Prepared: January 6, 2006

Applicant: Nexa Orthopedics, Inc., (dba Futura Biomedical, LLC)
10675 Sorrento Valley Road, Suite 100
San Diego, CA 92121

Telephone: 858-866-0660
Fax: 858-866-0661
Contact: Louise M. Focht

Device Name:	Nexa Compression Screw
Device Trade Name:	Nexa Compression Screw
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3040
Product Code:	87 HWC
Predicate Devices:	K043281, Wright Medical Charlotte High-Demand Compression Screw; K043102, Wright Medical Charlotte Multi-Use Compression Screw; and K040356 KMI Kompressor Compression Screw System
Registration Number:	2030833
Owner Operator Number:	9028319

Device Description

The Nexa Compression Screw is made of 316L Stainless Steel, per ASTM F138, and is intended to be implanted into the bones of the foot and hand, and bones appropriate for the size of the device. The screws are provided in three diameters of various lengths. No new materials are used in the development of this implant.

Indications for Use

The Nexa Compression Screw is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2006

Ms. Louisa M. Focht
Nexa Orthopedics, Inc.
10675 Sorrento Valley Road, Suite 100
San Diego, California 92121

Re: K060071
Trade/Device Name: Nexa Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: January 6, 2006
Received: January 9, 2006

Dear Ms. Focht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson,
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O.
f/t:NKM:rrr: 1/25/06

INDICATIONS FOR USE

510 (k) Number (If Known): K060071
Device Name: Nexa Compression Screw

Indications for Use

The Nexa Compression Screw is indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060071